DOLOGESIC NF- acetaminophen, dexbrompheniramine maleate tablet
Llorens Pharmaceutical International Division

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredients

(in each caplet)

Acetaminophen 500 mg

Dexbrompheniramine Maleate 1 mg

Purpose

Pain reliever/fever reducer

antihistamine

Uses

- For the temporary relief of minor aches and pains associated with
- headache
- muscular aches
- backaches
- minor arthritis pain
- common cold
- toothaches
- menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Sever liver damage may occur if you take

- more than 8 capsules in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminphen
- 3 or more alcoholic drinks every day while using this product

Alcohol Warning: If you consumer 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

Do not use

- with any other drug containing acetaminphen (prescription or non-prescription). If you are not sure whether a drug contains acetaminphen ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in the product
- for more than 10 days for pain, unless directed by a doctor
- for more than 3 days for fever, unless directed by a doctor
- May cause drowsiness: alcohol, sedative and tranquilizers may increase the drowsiness effect Avoid alcoholic beverages while taking this product
- Do not take this product if you are taking sedative or tranquilizers without consulting your doctore
- Use cauting when driving motor vehicle or operating machinery.

Ask a doctor or pharmacist before use:

- if you are taking the blood thinning drug warafin
- if you have liver disease

Stop using this product and ask a doctor if:

- pain gets worse or last more than 10 days
- fever gets worse or last more than 3 days
- new symptoms occur
- redness or swelling is present
- these could be signs of a serious condition

Keep out of reach of children

If you are pregnant or breast-feeding, ask a health professional before use.

Directions

Overdose Warning: Taking more than recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Do not exceed recommended dosage

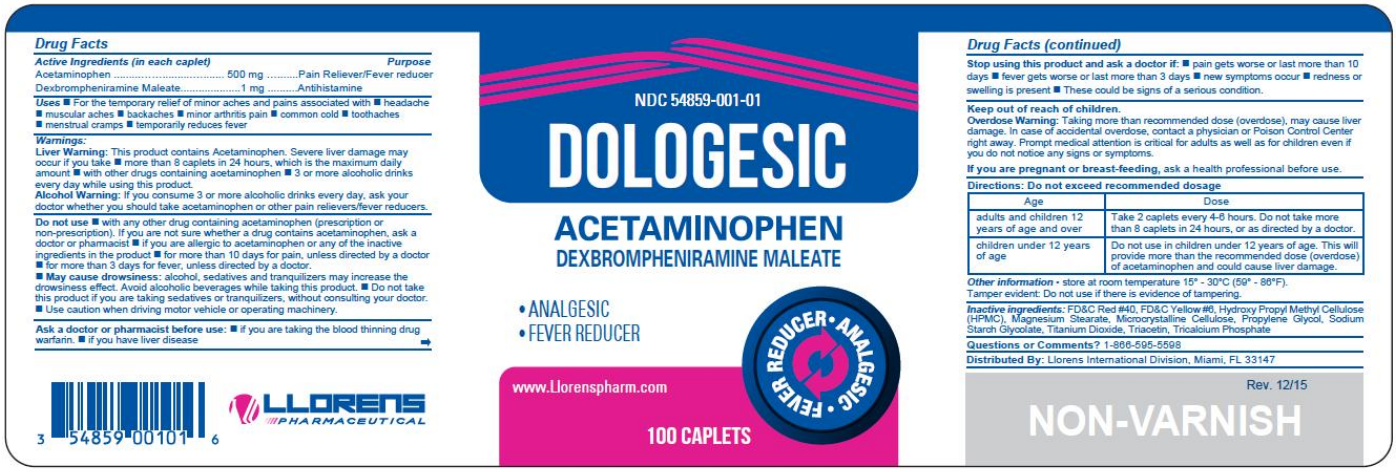
Age	Dose
adults and children 12 years of age and over	Take 2 caplets every 4-6 hours. Do not take more than 8 caplets in 24 hours, or as directed by a doctor
children under 12 years of age	Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminphen and could cause liver damage

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, hydrocypropyl methyl cellulose, magnesium stearate, microcrystaline cellulose, propylene glycol, sodium starch glycolate, titanium dioxide, triacetin, tricalcium phosphate

Questions or comments

1-866-595-5598



DOLOGESIC NF

acetaminophen, dexbrompheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	orange	**Score**	no score
Shape	capsule	**Size**	20mm
Flavor		**Imprint Code**	LLORENS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-001-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	
2	NDC:54859-001-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2016	

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020 Llorens Pharmaceutical International Division